

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Study of the effect of environmental and behavioral interventions on the pain of preterm neonates candidated for heel blood sampling in the neonatal intensive care unit

Protocol summary

Summary

The aim of this research is to study the effect of environmental and behavioral interventions on the pain of heel blood sampling in preterm infants. Materials and methods: A single-group clinical trial will be conducted. Thirty two infants with gestational age (GA) of 32-37 weeks will be evaluated in this study in both intervention and control stage. In the intervention stage, the effect of interventions such as noise reduction by ear-plugs, light reduction by blindfolds, reduction of nursing manipulation and creation of intrauterine position will be evaluated for neonates in the time period of 30 minutes before taking blood samples until 30 minutes after it. Then, the required information about the pain of newborns will be collected by the questionnaire measure in 5 stages (before interventions, two minutes before the blood sampling, during sampling, five minutes and 30 minutes after the sampling). In the control stage, no behavioral and environmental intervention will be performed, while the required information will be collected similar to the intervention stage. Inclusion criteria include: GA: 32-37 weeks; age below 7 days; giving no oxygen before and during interventions; receiving at least 2 orders of heel stick blood sampling during two continuous days.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015092024100N1**
Registration date: **2016-11-27, 1395/09/07**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-11-27, 1395/09/07

Registrant information

Name

fatemeh baharlooei

Name of organization / entity

isfahan univercity of medical science

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 2525

Email address

marofi@mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Isfahan University Of Medical Sciences

Expected recruitment start date

2015-10-23, 1394/08/01

Expected recruitment end date

2015-11-22, 1394/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the effect of environmental and behavioral interventions on the pain of preterm neonates candidated for heel blood sampling in the neonatal intensive care unit

Public title

The effects of developmental care on the pain that preterm infants suffer during heel blood sampling in neonatal intensive care unit

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria include: gestational age between 32-37 weeks; age below 7 days; hospitalized in neonatal intensive care unit; giving no oxygen before and during interventions; full consciousness; receiving at least 2 orders of heel blood sampling in two continuous days; not receiving anticonvulsants and anesthetic drugs; lack of diseases such as congenital defects, neurological disorders, bleeding into the ventricles of the brain, and seizure. Exclusion criteria include: Cancellation of participation in research by newborn parents; the need for oxygen therapy in children for any reason before and during the intervention.

Age

From **1 day** old to **7 days** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Isfahan University Of Medical Science

Street address

Isfahan University Of Medical Science, Azadi square,
Isfahan

City

Isfahan

Postal code

Approval date

2014-11-22, 1393/09/01

Ethics committee reference number

393862

Health conditions studied

1

Description of health condition studied

Preterm Neonate

ICD-10 code

xvi

ICD-10 code description

Certain conditions originating in the perinatal period

Primary outcomes

1

Description

The pain of heel blood sampling

Timepoint

Before intervention, two minutes before heel blood sampling, during heel blood sampling, five minutes after heel blood sampling and 30 minutes after heel blood sampling

Method of measurement

Infant Pain Scale (NIPS)

Secondary outcomes

empty

Intervention groups

1

Description

In the intervention stage, the effect of interventions such as noise reduction by ear-plugs, light reduction by blindfold, reduction of nursing manipulation and creation of intrauterine position will be measured for neonates in the time period of 30 minutes before taking blood samples until 30 minutes after it. In the control stage, no behavioral and environmental intervention will be performed.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Fatemeh Baharlooei

Street address

Shahid Beheshti Hospital, Felezi Bridge, Hakim
Nezami Avenue,

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan university of medical science

Full name of responsible person

Dr.taleghani

Street address

Isfahan

City

Isfahan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Isfahan university of medical science

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact**Name of organization / entity**

Isfahan Univercity Of Medical Sceince

Full name of responsible person

Fatemeh Baharlooei

Position

license/Nurse

Other areas of specialty/work**Street address**

No. 11, Farid Alley, Motahhari Alley, Vahid Street,

City

Isfahan

Postal code**Phone**

+98 31 3775 3779

Fax**Email**

f.baharlooei@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Isfahan University Of Medical Sceince

Full name of responsible person

Maryam Marofi

Position

Master Of Science

Other areas of specialty/work**Street address**

Isfahan University Of Medical Sceince, University of Isfahan, Azadi square, Isfahan

City

Isfahan

Postal code**Phone**

+31 37922525

Fax**Email**

marofi@mui.ac.ir

Web page address

Person responsible for updating data

Contact**Name of organization / entity****Full name of responsible person**

Fatemeh Baharlooei

Position**Other areas of specialty/work****Street address**

No. 11, Farid Alley, Motahhari Alley, Vahid Street,

City

Isfahan

Postal code**Phone**

+98 31 3775 3779

Fax**Email**

f.baharlooei@yahoo.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty